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# PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Article 36 and Rule 70)



REC'D 05 MAR 2004

Applicant's or agent's file reference 142624.6 DK	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/IL 03/00026	International filing date (day/month/year) 08.01.2003	Priority date (day/month/year) 08.01.2002
International Patent Classification (IPC) or both national classification and IPC A01N1/02		
Applicant I.M.T. INTERFACE MULTIGRAD TECHNOLOGY LTD et al.		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 6 sheets, including this cover sheet.  
  
☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).  
  
 These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand  20.07.2003	Date of completion of this report  02.03.2004
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**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

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International application No.

PCT/IL 03/00026

**I. Basis of the report**

1. With regard to the **elements** of the international application (Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)):

**Description, Pages**

1-26

as originally filed

**Claims, Numbers**

5-77

as originally filed

1-4

filed with telefax on 01.12.2003

**Drawings, Sheets**

1/2-2/2

as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

see separate sheet

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 63-77

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 63-77

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	1-45,50-53,55-62
	No: Claims	46-49,54
Inventive step (IS)	Yes: Claims	1-45,50-53,55-62
	No: Claims	46-49,54
Industrial applicability (IA)	Yes: Claims	1-62
	No: Claims	

2. Citations and explanations

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**see separate sheet**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IL03/00026

**Re Item I**

**Basis of the report**

The documents mentioned in this International Preliminary Examination Report are numbered in accordance with the order they appear in the International Search Report.

The amendments filed with the telefax of the 01.12.03 comply with Article 34(2)b PCT, insofar as they do not introduce any subject-matter which extends beyond the application as originally filed. They are thus admissible.

**Re Item III**

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

As no search report has been established for the claims 63-77, the present opinion solely concerns the filed claimed 1-62.

**Re Item V**

**Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Lack of clarity is objected insofar as the conciseness requirement is not met by the claims. Actually, the term "concise" as it can be read in Art. 6 and Rule 6.1(a) PCT and in the PCT Guidelines PG-III 5.1, should be interpreted not only as a requirement to shorten each Claim individually, but also to reduce as much as possible the number of Claims.

The present invention relates to a method for freezing/thawing samples of larger dimensions compared to straws used for biological samples (e.g. semen) and to an apparatus therefor.

D1 describes a method for thawing biological specimens comprising a first step of warming the sample by exposing it to an intermediate temperature. The counterpart of this first step in the present invention is divided in 2 sub-steps, namely subjecting first the sample to a gradient of temperature until a part of the sample reaches the intermediate temperature and then exposing the sample to the intermediate temperature.

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IL03/00026

D2 relates to methods and apparatus for changing the temperature of a sample of the dimensions of a straw. The heat transfer within the sample perpendicularly to the axis of the straw can be considered to be uniform, due to the relatively small diameter of the sample. The device described in D2 appears to anticipate present claims 46-49 and 54, because the difference in sample size, which has an influence on how the device is constructed, does not appear in the present claims 46-49 and 54. The dimension of more than 0.5 cm in 2 perpendicular cross-sections is an essential feature of the present invention and is indeed directly linked the problem to be solved with respect to D2, i.e. to provide an apparatus for freezing larger (thicker) samples. All independent claims should contain this feature.

D3 relates to a method for freezing samples adapted for larger samples (over 50ml). This method implies 2 intermediate temperatures but not the use of an gradient of temperature.

With the exception of claims 46-49 and 54 as mentioned above, the present application fulfills the criteria of Article 33(2) PCT, because the claimed subject-matter is new with respect to the prior art as defined in Rule 64(1) to (3) PCT.

Assuming the lack of novelty above can be overcome, the present application would fulfill the criteria of Article 33(3) PCT, because the claimed subject-matter would involve an inventive step (Rule 65(1) and (2) PCT).

The present invention fulfills the criteria of Article 33(4) PCT, because the subject-matter of the present claims is industrially applicable.

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SUBSTITUTE SHEET

**CLAIMS:**

1. A method for changing the temperature of a sample from an initial temperature via an intermediate temperature to a final temperature, one of the initial and final temperatures being above the freezing point of said sample and the other being below the freezing point, the minimal dimension of the sample in each of two mutually perpendicular cross-sections exceeding 0.5 centimeters, and at least one of the cross-sections having an outer zone and an inner zone, the method comprising:
  - (i) changing the temperature of the sample by subjecting it to a temperature gradient from the initial temperature to the intermediate temperature until the temperature of the sample in at least one part of the outer zone equals the intermediate temperature whilst the temperature of the sample in the inner zone or in another part of the outer zone, spaced from said one part, is different from said intermediate temperature;
  - (ii) further changing the temperature of said sample by subjecting it to the intermediate temperature until the temperature of said sample in at least one cross-section is uniform and equals the intermediate temperature; and
  - (iii) changing the temperature of said sample until the majority of said sample is at the final temperature.
2. The method of Claim 1, wherein said sample is subjected in step (ii) to said intermediate temperature until the temperature of the sample equals said intermediate temperature.
3. The method according to anyone of Claims 1 or 2, wherein the changing of the temperature in step (i) is achieved by moving the sample through a region with a temperature gradient from the initial temperature to the intermediate temperature, and the changing of the temperature in step (iii) is achieved by moving the sample through a region with a temperature gradient from the intermediate temperature to the final temperature.
4. The method of Claim 3, wherein said changing of the ambient temperature is at least partially gradual and is achieved at least partially by the gradual movement of said sample in the direction of a temperature gradient.